

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0671732	(X3) Date Survey Completed 01/31/2022
Name of Provider or Supplier Laboratorio Clinico Levittown	Street Address, City, State Lealtad S 15 Levittown Station, Toa Baja, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on General Immunology (Mycoplasma Pneumoniae test) quality control records review (2020-2021) and interview with the laboratory supervisor on January 31, 2022 at 3:15 PM , it was determined that the laboratory failed to include a negative and positive external control material when performed Mycoplasma Pneumoniae test by Immuno Card method. The findings include : a. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method. b. Mycoplasma quality control logs were reviewed from 8/2021 to 11/2021. c. The records showed that the laboratory did not include a negative and positive external control material from August, 2021 to November, 2021. d. The laboratory performed and reported 11 patient samples from August 16, 2021 to November 4, 2021. e. The laboratory supervisor confirmed on January 31, 2022 at 3:15 P.M., that the laboratory failed to include a negative and positive external control material each day of testing when performed Mycoplasma Pneumoniae test by Immuno Card method.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently,</p>

and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Immuno Card Mycoplasma testing records and laboratory supervisor interview on January 31, 2022 at 3:15 PM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the laboratory did not run an external negative and positive control material each day of patient testing from August 16, 2021 to November 4, 2021. Refer D5449